REMARKS

In the Office Action, claim 28 is objected to; claims 4 and 6-9 are rejected under 35 U.S.C. § 102 in view of U.S. Patent No. 5,223,285 ("DeMichele"); claims 3 and 26-28 are rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,166,189 ("Trimbo"); claims 1, 3-4, 6-11, 13-14, 23-24, 26-27 and 29-33 are rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 6,008,248 ("Pscherer"); and claims 1, 10, 13-15, 29 and 31-34 are rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,080,787 ("Carlson"). Applicants believe that the rejections have been overcome in view of the amendments and/or at least for the reasons set forth below.

With respect to the objection to claim 28, this claim has been canceled without prejudice or disclaimer and thus the objection has been rendered moot and should therefore be withdrawn in view of same.

With respect to the rejections in view of DeMichele or Trimbo, the claims at issue with respect to same except for Claim 9 have been canceled without prejudice or disclaimer and thus the rejections should be rendered moot as well and therefore withdrawn. Regarding Claim 9, this claim depends from independent Claim 1 and thus as a matter of law incorporates the features of independent Claim 1. As Claim 1 has not been rejected for alleged anticipation reasons in view of DeMichele, Applicants believe that the rejection of Claim 9 is improper at least based on its dependency of Claim 1.

Accordingly, the anticipation rejections in view of DeMichele or Trimbo should be withdrawn.

As previously discussed, claims 1, 3-4, 6-11, 13-14, 23-24, 26-27 and 29-33 have been rejected as allegedly anticipated by Pscherer. At the outset, claims 3-4, 6-8, 23-24, 26 and 27 have been cancelled without prejudice or disclaimer and thus the rejection in view of Pscherer with respect to same should be rendered moot. Of the remaining pending claims at issue, claims 1 and 10 are the sole independent claims. Applicants believe that the anticipation rejection in view of Pscherer with respect to same is improper.

Claim 1 recites a method of treating sepsis. The method includes administering to a patient with sepsis a therapeutically effective amount of a composition which includes at least one lipid wherein the lipid that provides about 75% or less of the total energy of the composition

wherein the composition includes a n-6/n-3 fatty acid ratio of about 2/1 to about 7/1, and wherein the composition includes a protein source and a carbohydrate source. Claim 10 recites a method of treating inflammatory shock. The method includes administering to a patient that suffers from inflammatory shock a therapeutically effective amount of a composition that includes at least one lipid wherein the lipid provides about 75% or less of the total energy of the composition and wherein the composition includes a n-6/n-3 fatty acid ratio of about 2/1 to about 7/1 and wherein the composition includes a protein source and a carbohydrate source.

The present invention, in general, relates to the use of a composition, such as an enteral composition, with a relatively high and specified lipid content in the treatment of sepsis and inflammatory shock. As such, the composition as claimed can treat sepsis and inflammatory shock and also provide complete nutrition to the patient. This discovery goes against conventional thinking in the art as it was previously understood that dietary lipids could not be properly metabolized under such conditions.

Applicants believe that Pscherer is distinguishable from the claimed invention. Pscherer relates to liquid emulsions that include medium-chain triglycerides, vegetable oils and fish oil and their use for parenteral nutrition. Yet, Pscherer merely provides that lipids are the only macronutrient present in the formulations. Clearly, this fails to suggest both treatment in addition to complete nutrition in contrast to the claimed compositions that have a relatively high and specified lipid profile for treatment purposes in addition to providing complete nutrition. Indeed, the claimed composition also includes a protein source and a carbohydrate source as previously discussed.

Further, it is generally understood and recognized by those skilled in the art that enteral nutrition is preferred to parenteral nutrition unless the patient is unable to tolerate enteral nutrition. As such, the claimed methods represent a significant advance over Pscherer. As previously discussed, the inventors have unexpectedly discovered that a relatively high quantity of lipids can be delivered enterally where further the lipids can be digested by the patients that suffer from inflammatory shock or sepsis, thus providing treatment as well as complete nutrition to the patient. This allows patients suffering from such conditions who previously had to be subjected to parenteral nutrition to be feed now via the enteral route. Nowhere does Pscherer

provide a shift from parenteral administration to enteral administration of its emulsions, let alone to treat sepsis and/or inflammatory shock while providing complete nutrition to the patient.

Based on at least these reasons, Applicants believe that Pscherer is distinguishable from the claimed invention. Therefore, Applicants respectfully submit that Pscherer fails to anticipate the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1, 10, 13-15, 29 and 31-34 are rejected under 35 U.S.C. § 103 in view of Carlson. Of the pending claims at issue, claims 1 and 10 are the sole independent claims as previously discussed. Applicants believe that Carlson on its own is distinguishable from the claimed invention.

At the outset, Carlson relates to a method for reducing the incidence of necrotizing enterocolitis in infants. This is allegedly done through the administration of long-chain polyunsaturated fatty acids (PUFA) so as to provide at least one milligram of n6 PUFA per day. Clearly, necrotizing enterocolitis in infants is such a specialized condition that one skilled in the art would not consider it when faced with the problem of designing a nutritional composition for patients that suffer from inflammatory shock or sepsis as claimed. Moreover, Applicants believe that the lipid profile of the Carlson compositions are different than those as claimed. Again, the claimed invention is directed to a nutritional composition, such as an enteral composition, with a relatively high and specified lipid content in the treatment of sepsis and inflammatory shock while also providing complete nutrition to the patent. Based on at least these reasons, Applicants believe that Carlson is distinguishable from and thus fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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Dated: January 21, 2005